



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Carlsson, et al.

Application No.

09/734,801

Attorney Docket No.

0046-PO2386US0

Filed:

December 12, 2000

For:

A METHOD FOR IN VITRO MOLECULAR
EVOLUTION OF PROTEIN FUNCTION

Examiner:

Chunduru, Suryaprabha

Group Art Unit:

1637

CERTIFICATE OF MAILING UNDER 37 C.F.R § 1.8(a)

I hereby certify that this Correspondence is being deposited on the date identified below with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER FOR PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450.

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97**

In accordance with the provisions of 37 C.F.R. §1.56, Applicant hereby submits the attached Form PTO-1449 listing additional references which the Patent Examiner is requested to consider and make of record in the above-identified application. Copies of each of the listed references are enclosed herewith. This submission is believed to be in full compliance with the requirements of 37 CFR §§1.97 and 1.98.

In accordance with 37 C.F.R. §1.97(c), enclosed herewith is the required fee of \$180.00, as set forth in 37 C.F.R. §1.17(p). In event that an additional fee is required, the Commissioner is authorized to charge the Deposit Account No.

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04-1406 of the undersigned attorneys. A duplicate copy of this sheet is enclosed.

In the opinion of the undersigned, the references submitted herewith, together with those previously submitted with the Information Disclosure Statement filed January 17, 2002 and May 29, 2003, are the most pertinent of which the undersigned is aware. However, no representation is made or intended that more pertinent references do not exist.

This submission is not an admission that the references listed on the attached Form PTO-1449 constitute prior art against the claims of this application.

Several references included on the PTO Form 1449 are of record in the present application since they have been submitted previously to the United States Patent and Trademark Office in an Information Disclosure Statement. Copies of these references from the previous Information Disclosure Statement are not included. Those references include: A2, A3, A11, A12, A19, A25, A38, A39, A45, B3, B6, B7, B10, B34, B37, C7, C8, C11, C14, C16, C17, C22, C26, C29 and C30.

The Examiner is respectfully requested to confirm receipt and consideration of the cited references by initialing and returning a copy of the attached Form PTO-1449 in accordance with MPEP §609.

Early and favorable consideration of this application is respectfully requested.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN
A Professional Corporation
Attorneys for Applicant(s)

By



Kathleen D. Rigaut, Ph.D., J.D.

PTO Registration No. 43,047

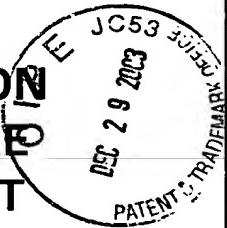
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Facsimile: (215) 563-4044

Enclosures - Form PTO-1449

Copies of references listed on PTO - 1449

INFORMATION DISCLOSURE STATEMENT



SHEET 1 OF 9

Complete if known

Application Number: 09/734,801

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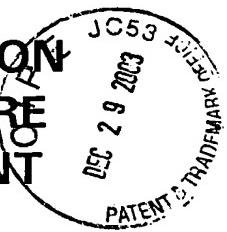
UNITED STATES PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE MM-DD-YYYY	FIRST NAMED INVENTOR
	A1	4,888,286	12-19-1989	Crea
	A2	5,023,171	06-11-1991	Ho et al.
	A3	5,252,479	10-12-1993	Srivastava
	A4	5,270,170	12-14-1993	Schatz et al.
	A5	5,338,665	08-16-1994	Schatz et al.
	A6	5,491,074	02-13-1996	Aldwin et al.
	A7	5,498,530	03-12-1996	Schatz et al.
	A8	5,512,463	04-30-1996	Stemmer
	A9	5,514,568	05-07-1996	Stemmer
	A10	5,521,291	05-28-1996	Curiel et al.
	A11	5,573,907	11-12-1996	Carrino et al.
	A12	5,605,793	02-25-1997	Stemmer
	A13	5,712,089	01-27-1998	Borrebaeck et al.
	A14	5,723,323	03-03-1998	Kauffman et al.
	A15	5,733,731	03-31-1998	Schatz et al.
	A16	5,733,753	03-31-1998	Jørgensen
	A17	5,763,192	06-09-1998	Kauffman et al.
	A18	5,798,208	08-25-1998	Crea
	A19	5,811,238	09-22-1998	Stemmer et al.
	A20	5,814,476	09-29-1998	Kauffman et al.
	A21	5,817,483	10-06-1998	Kauffman et al.
	A22	5,824,514	10-20-1998	Kauffman et al.

EXAMINER'S SIGNATURE	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw a line through citation if citation not in conformance and reference not considered. Include a copy of this form with next communication to applicant.

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	A23	5,830,650	11-03-1998	Crea
	A24	5,830,696	11-03-1998	Short
	A25	5,830,721	11-03-1998	Stemmer et al.
	A26	5,834,252	11-10-1998	Stemmer et al.
	A27	5,837,458	11-17-1998	Minshull et al.
	A28	5,858,657	01-12-1999	Winter et al.
	A29	5,858,725	01-12-1999	Crowe et al.
	A30	5,871,907	02-16-1999	Winter et al.
	A31	5,925,544	07-20-1999	Jørgensen
	A32	5,928,905	07-27-1999	Stemmer et al.
	A33	5,939,250	08-17-1999	Short
	A34	5,965,408	10-12-1999	Short
	A35	5,969,108	10-19-1999	McCafferty et al.
	A36	5,976,862	11-02-1999	Kauffman et al.
	A37	6,096,548	08-01-2000	Stemmer
	A38	6,117,679	09-12-2000	Stemmer
	A39	6,132,970	10-17-2000	Stemmer
	A40	6,143,527	11-07-2000	Pachuk et al.
	A41	6,153,410	11-28-2000	Arnold et al.
	A42	6,156,511	12-05-2000	Schatz et al.
	A43	6,159,687	12-12-2000	Vind
	A44	6,159,688	12-12-2000	Borchert, et al.
	A45	6,159,690	12-12-2000	Borrebaeck et al.

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FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	DOCUMENT NUMBER	COUNTRY OR REGION	DATE OF PUBLICATION MM-DD-YYYY	FIRST NAMED INVENTOR OR APPLICANT
	B1	WO 86/05803	PCT	10-09-1986	Ballivet, Kauffman
	B2	EP 0 368 684 A	EP	05-16-1990	Medical Research Council
✓	B3	EP 0 415 731 A	EP	03-06-1991	The Wellcome Foundation Limited
	B4	EP 0 456 304 A	EP	11-13-1991	Eastman Kodak Company
	B5	EP 0 590 689 A	EP	04-06-1994	Ballivet, Kauffman
	B6	WO 90/07936	PCT	07-26-1990	Chiron Corporation
	B7	WO 90/14430	PCT	11-29-1990	Scripps Clinic and Research Foundation
	B8	WO 92/01047	PCT	01-23-1992	Cambridge Antibody Technology Limited
	B9	WO 92/15702	PCT	09-17-1992	Bradbury
	B10	WO 93/07282	PCT	04-15-1993	Boehringer Ingelheim International GMBH
	B11	WO 93/08278	PCT	04-29-1993	Affymax Technologies N.V.
	B12	WO 93/12257	PCT	06-24-1993	Hybridtech Incorporated
	B13	WO 94/12632	PCT	06-09-1994	University College London
	B14	WO 94/28173	PCT	12-08-1994	Affymax Technologies N.V.
	B15	WO 95/22625	PCT	08-24-1995	Affymax Technologies N.V.
✓	B16	WO 96/05803	PCT	02-29-1996	Quest International B.V.
	B17	WO 96/17056	PCT	06-06-1996	Institut Pasteur
	B18	WO 96/40750	PCT	12-19-1996	Glaxo Group Limited
	B19	WO 96/40987	PCT	12-19-1996	Affymax Technologies N.V.
	B20	WO 97/07205	PCT	02-27-1997	Novo Nordisk A/S

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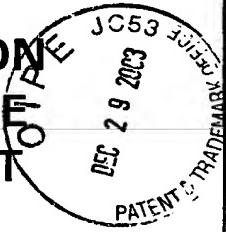
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	B21	WO 97/07206	PCT	02-27-1997	Novo Nordisk A/S
	B22	WO 97/08320	PCT	03-06-1997	Morphosysgesellschaft für Proteinoptimierung MBH
	B23	WO 97/20078	PCT	06-05-1997	Affymax Technologies N.V.
✓	B24	WO 97/35957	PCT	10-02-1997	Maxygen, Inc.
✓	B25	WO 97/35966	PCT	10-02-1997	Maxygen, Inc.
✓	B26	WO 98/01581	PCT	01-15-1998	Recombinant Biocatalysis, Inc.
✓	B27	WO 98/05765	PCT	02-12-1998	Novo Nordisk A/S
✓	B28	WO 98/13485	PCT	04-02-1998	Maxygen, Inc.
	B29	WO 98/13487	PCT	04-02-1998	Maxygen, Inc.
	B30	WO 98/25965	PCT	06-18-1998	Glaxo Group Limited
	B31	WO 98/27230	PCT	06-25-1998	Maxygen, Inc.
	B32	WO 98/28416	PCT	07-02-1998	Novo Nordisk A/S
	B33	WO 98/31837	PCT	07-23-1998	Maxygen, Inc.
	B34	WO 98/32845	PCT	07-30-1998	Bioinvent International AB
	B35	WO 98/41622	PCT	09-24-1998	Novo Nordisk A/S
	B36	WO 98/41623	PCT	09-24-1998	Novo Nordisk A/S
	B37	WO 98/58080	PCT	12-23-1998	Bioinvent International AB
	B38	WO 99/21979	PCT	05-06-1999	Maxygen, Inc.
✓	B39	WO 99/23107	PCT	05-14-1999	Maxygen, Incorporated
	B40	WO 99/23236	PCT	05-14-1999	Diversa Corporation
	B41	WO 99/33965	PCT	07-08-1999	Diatech Pty. Ltd.
	B42	WO 99/41368	PCT	08-19-1999	Maxygen, Inc.
	B43	WO 99/41369	PCT	08-19-1999	Maxygen, Inc.
	B44	WO 99/41383	PCT	08-19-1999	Maxygen, Inc.
	B45	WO 99/41402	PCT	08-19-1999	Maxygen, Inc.
	B46	WO 99/45110	PCT	09-10-1999	Diatech Pty. Ltd.
	B47	WO 99/57128	PCT	11-11-1999	Maxygen, Inc.

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	B48	WO 99/58661	PCT	11-18-1999	Diatech Pty. Ltd.
	B49	WO 99/65927	PCT	12-23-1999	Maxygen, Inc.
	B50	WO 00/04190	PCT	01-27-2000	Maxygen, Inc.
✓	B51	WO 00/09679	PCT	02-24-2000	Proteus
✓	B52	WO 00/09727	PCT	02-24-2000	Maxygen, Inc.
✓	B53	WO 00/12680	PCT	03-09-2000	Maxygen, Inc.
✓	B54	WO 00/18906	PCT	04-06-2000	Maxygen, Inc.
✓	B55	WO 00/20573	PCT	04-13-2000	Maxygen, Inc.
✓	B56	WO 00/28008	PCT	05-18-2000	Maxygen, Inc.
✓	B57	WO 00/28017	PCT	05-18-2000	Maxygen, Inc.
✓	B58	WO 00/28018	PCT	05-18-2000	Maxygen, Inc.
✓	B59	WO 00/34512	PCT	06-15-2000	Proteus
✓	B60	WO 00/42559	PCT	07-20-2000	Maxygen, Inc.
✓	B61	WO 00/42560	PCT	07-20-2000	Maxygen, Inc.
✓	B62	WO 00/42561	PCT	07-20-2000	Maxygen, Inc.
✓	B63	WO 00/46344	PCT	08-10-2000	Diversa Corporation
✓	B64	WO 00/52155	PCT	09-08-2000	Maxygen, Inc.
✓	B65	WO 00/53744	PCT	09-14-2000	Diversa Corporation
✓	B66	WO 00/58517	PCT	10-05-2000	Diversa Corporation
	B67	WO 00/61731	PCT	10-19-2000	Maxygen, Inc.
✓	B68	WO 00/61740	PCT	10-19-2000	Maxygen, Inc.
✓	B69	WO 00/72013	PCT	11-30-2000	The Penn State Research Foundation
✓	B70	WO 00/73433	PCT	12-07-2000	Novo Nordisk A/S
✓	B71	2000-308490 A	Japan	11-07-2001	Maxygen, Inc.
✓	B72	10-66576	Japan Publication	03-10-1998	Novo Nordisk Aktie Selskab
✓	B73	2813314	France	03-01-2002	Biomethodes

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OTHER PRIOR ART - NON-PATENT DOCUMENTS

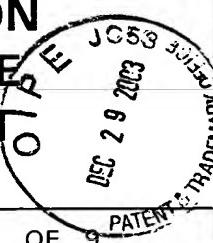
EXAMINER'S INITIALS	CITE NO.	Include name of the author (in Capital Letters), title of the article (when appropriate), title of the item(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C1	Berger, et al., "Expanding the Potential of Restriction Endonucleases: Use of Hapaxterministic Enzymes", Anal. Biochem. 222:1-8, (1994)
	C2	Cadwell, et al., "Randomization of Genes by PCR Mutagenesis", PCT Methods Appl., 2:28-33, (1992)
	C3	Cadwell, et al., "Mutagenic PCR", PCT Methods Appl., 3:S136-140, (1994)
	C4	Casson & Manser, "Evaluation of Loss and Change of Specificity Resulting from Random Mutagenesis of an Antibody V _H Region", J. Immunol. 155: 5647-5654 (1995)
	C5	Chalfie, et al., "Green Fluorescent Protein as a Marker for Gene Expression", Science 263: 802-805 (1994)
	C6	Chen, et al., "Tuning the activity of an enzyme for unusual environments: Sequential random mutagenesis of subtilisin E for catalysis in dimethylformamide", Proc. Natl. Acad. Sci. USA 90: 5618-5622 (1993)
	C7	Cramer, et al., "DNA shuffling of a family of genes from diverse species accelerates directed evolution", Nature, 391: 288-291 (1998)
	C8	Deng, et al., "Simultaneous randomization of antibody CDRs by a synthetic ligase chain reaction strategy", Nucl. Acid Res. 21: 4418-4419, (1993)
	C9	Engberg, et al., "Phage-Display Libraries of Murine and Human Antibody Fab Fragments", Molecular Biotechnology 6: 287-310, (1996)
	C10	Giver, et al., "Directed evolution of a thermostable esterase", Proc. Natl. Acad. Sci. USA 95: 12809-12813, (1998)
	C11	Gram, et al., "In vitro selection and affinity maturation of antibodies from a naive combinatorial immunoglobulin library", Proc. Natl. Acad. Sci. USA 89: 3576-3580, (1992)
	C12	Hansson, et al., "Evolution of Differential Substrate Specificities in Mu Class Glutathione Transferases Probed by DNA Shuffling", J. Mol. Biol. 287: 265-276, (1999)

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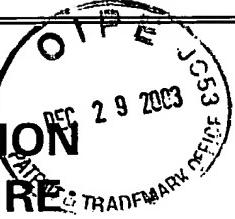
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C13	Henke & Bornscheuer, "Directed Evolution of an Esterase from <i>Pseudomonas fluorescens</i> . Random Mutagenesis by Error-Prone PCR or a Mutator Strain and Identification of Mutants Showing Enhanced Enantioselectivity by a Resorufin-Based Fluorescence Assay", <i>Biol. Chem.</i> , 380: 1029-1033, (1999)
C14	Ho, et al., "Site-directed mutagenesis by overlap extension using the polymerase chain reaction", <i>Gene</i> 77: 51-59, (1989)
C15	Hoogenboom, et al., "By-passing Immunisation: Human Antibodies from Synthetic Repertoires of Germline V _H Gene Segments Rearranged in Vitro", <i>J. Mol. Biol.</i> 227: 381-388, (1992)
C16	Horton, et al., "Engineering hybrid genes without the use of restriction enzymes: gene splicing by overlap extension", <i>Gene</i> , 77: 61-68, (1989)
C17	Jansen, et al., "Disruption of phase during PCR amplification and cloning of heterozygous target sequences", <i>NAR</i> , 18: 5153-5156, (1990)
C18	Kikuchi, et al., "Novel family shuffling methods for the in vitro evolution of enzymes", <i>Gene</i> 236: 159-167, (1999)
C19	Kobayashi, et al., "Analysis of Assembly of Synthetic Antibody Fragments: Expression of Functional scFv with Predefined Specificity", <i>Biotechniques</i> , 23: 500-503, (1997)
C20	Kwekkeboom, et al., "CD40 plays an essential role in the activation of human B cells by murine EL4B5 cells", <i>Immunol.</i> 79: 439-444, (1993)
C21	Lewin, "Genes IV", page 272, Oxford University Press, (1990)
C22	Lewis & Crowe, "Immunoglobulin complementary-determining region grafting by recombinant polymerase chain reaction to generate humanised monoclonal antibodies", <i>Gene</i> 101: 297-302 (1991)
C23	Liu, et al., "Replacement and deletion mutations in the catalytic domain and belt region of <i>Aspergillus awamori</i> glucoamylase to enhance thermostability", <i>Protein Eng.</i> 13: 655-659 (2000)
C24	Luqmani & Lymboura, "Subtraction Hybridization Cloning of RNA Amplified From Different Cell Populations Microdissected From Cryostat Tissue Sections", <i>Anal. Biochem.</i> , 222: 102-109, (1994)

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C25	May, et al., "Inverting enantioselectivity by directed evolution of hydantoinase for improved production of L-methionine", Nat. Biotechnol. 18: 317-320, (2000)
C26	Meyerhans, et al., "DNA recombination during PCR", Nucl. Acid Res., 18: 1687-91, (1990)
C27	Moore, et al., "Directed evolution of a para-nitrobenzyl esterase for aqueous-organic solvents", Nature Biotechnology, 14: 458-467 (1996)
C28	Orlandi, et al., "Cloning immunoglobulin variable domains for expression by the polymerase chain reaction", Proc. Natl. Acad. Sci. USA, 86: 3833-3837 (1989)
C29	Paabo, et al., "Ancient DNA and the Polymerase Chain Reaction", J. Biol. Chem., 264: 9709-9712, (1989)
C30	Paabo, et al., "DNA Damage Promotes Jumping between Templates during Enzymatic Amplification", J. Biol. Chem., 265: 4718-4721, (1990)
C31	Prickett, et al., "A Calcium-Dependent Antibody for Identification and Purification of Recombinant Proteins", BioTechniques, 7: 580-589, (1989)
C32	Roberts, et al., "Generation of an antibody with enhanced affinity and specificity for its antigen by protein engineering", Nature, 328: 731-734, (1987)
C33	Schmidt-Dannert, et al., "Molecular breeding of carotenoid biosynthetic pathways", Nat. Biotechnol., 18: 750-753, (2000)
C34	Shyur, et al., "Site-directed Mutagenesis of Residues at Subunit Interfaces of Procine Fructose-1,6-bisphosphatase", J. Biol. Chem., 271: 3005-3010, (1996)
C35	Söderlind, et al., "Domain libraries: Synthetic diversity for de novo design of antibody V-regions", Gene, 160: 269-272, (1995)
C36	Song, et al., "Simultaneous Enhancement of Thermostability and Catalytic Activity of Phospholipase A ₁ by Evolutionary Molecular Engineering", Appl. Environ. Microbiol. 66: 890-894, (2000)
C37	Volkov, et al., "Methods for in Vitro DNA Recombination and Random Chimeragenesis", Methods Enzymol., 328: 447-456 (2000)
C38	Wan, et al., "In vitro evolution of horse heart myoglobin to increase peroxidase activity", Proc. Natl. Acad. Sci. USA, 95: 12825-12831 (1998)

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	C39	Zhao & Arnold, "Directed evolution converts subtilisin E into a functional equivalent of thermitase", Protein Eng., 12: 47-53, (1999)
	C40	Zhao, et al., "Molecular evolution by staggered extension process (StEP) in vitro recombination", Nat. Biotechnol. 16: 258-261 (1998)

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